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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,460	08/19/1998	HERMAN WALDMANN	1283-36	7809

7590 08/13/2004

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/125,460

Applicant(s)

WALDMANN ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,26-29,31-35,37-58,60-69 and 71-75 is/are pending in the application.
- 4a) Of the above claim(s) 18,71 and 72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-29,31-35,37-58,60-69 and 73-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date 6/25/04
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claim 26 has been amended.
2. Claims 18, 71-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in Paper No. 28.
3. Claims 26-29, 31-35, 37-58, 60-69 and 73-75 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

### ***Response to Arguments***

5. The rejection of claims 26-29, 31-35, 37-58, 60-69 and 73-75 under 35 U.S.C. 103(a) as being unpatentable over Isaacs et al (Therapeutic Immunology 1:303-312, 1994, IDS #5) and further in view of Carter et al (U.S. Patent 6,054,297, CON to 1992) and Rudikoff et al (PNAS 79:1979-1983, 1982) is maintained.

The response filed 6/1/04 has been carefully considered but is deemed not to be persuasive. The response states that the foregoing amendments are deemed to overcome the Examiner's position by requiring that the non-cell binding antibody is a single antibody (see page 13 of response). In response to this argument, the claims are directed to producing a non-cell binding antibody that has 4 properties which the combination of references in the 103 rejection would obviously produce. The claims are to producing an antibody not administration of a single antibody. The combination of references would produce the non-cell binding antibody as required in the claims.

The response further states the distinction between the method of Carter and the present invention is that humanization is to render the therapeutic antibody as similar as possible to a human antibody to reduce immunogenicity and the present invention aims to present epitopes within the antibody that induces tolerance instead of reactivity to those epitopes and humanization aims to avoid an immune response and the present method is used to make the host tolerant to a potentially foreign peptide (see page 14 of the response). In response to this argument, it still appears that the outcome is the same because humanization seeks to reduce the immune response to regions of the antibody which are "foreign" and the present invention is to make a host tolerant to an antibody ("foreign peptide") which is the same outcome as Carter.

The response further states that the Examiner cites Rudikoff et al as evidence that changing a single amino acid in a CDR can eliminate antigen binding and the term "antigen" in Rudikoff is not correct and an antigen is a macromolecule not a hapten as in Rudikoff et al and an antibody to a "antigen" involves multiple contacts with the antigen and cites Amit for multiple residues and at the time of the invention it is the complexity in this multiple contacts that the single substitutions in a non-hapten antibodies would not be capable of eliminating or significantly reducing antigen binding (see pages 14-17 of response). In response to this argument, Rudikoff et al teach an antigen and an antibody to such. The specification does not limit an "antigen" to a macromolecule or any specific molecule or number of amino acids or even a peptide or polypeptide. Rudikoff et al clearly teach an antigen and recites the term antigen as the molecule that the antibody binds to and as such this meets the limitation. Whether there are multiple

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contacts to an antigen or not is not the issue, the reference teaches alteration in a CDR that eliminates binding. The reference demonstrates that well before the time of the claimed invention it was known that alteration of residue(s) in the CDR can alter antigen binding as required in the claim.

### ***Conclusion***

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571)

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272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, <sup>JEFFREY SIKW</sup> ~~Christina Chan~~, can be reached on (571) 272-<sup>0787</sup>~~0841~~.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832

  
LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER